

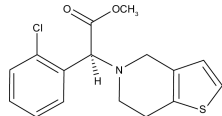
# DUXOREL

## (CLOPIDOGREL)

75mg Tablet

### DESCRIPTION:

**Clopidogrel** is an antiplatelet medication used to reduce the risk of heart disease and stroke in those at high risk. It is also used together with aspirin in heart attacks and following the placement of a coronary artery stent (dual antiplatelet therapy). It is taken by mouth. Onset of effects is about two hours and lasts for five days. The empirical formula is  $C_{16}H_{16}ClNO_2S$  and its molecular weight is 321.8 g/mol.



### COMPOSITION:

Each film coated tablet contain Clopidogrel Bisulfate equivalent to Clopidogrel .....75mg.

### CLINICAL PHARMACOLOGY:

#### Pharmacokinetics

Absorption and distribution: **Duxorel** is rapidly absorbed after oral administration of repeated doses of 75-milligram Clopidogrel (base), with peak plasma levels (about 3 mg/l) of the main circulating metabolite occurring around one hour after dosing. The pharmacokinetics of the main circulating metabolite are linear (plasma concentrations increased in proportion to dose) in the dose range of 50 to 150 mg of **Duxorel**. Absorption is at least 50% based on urinary excretion of **Duxorel** related metabolites.

Metabolism and elimination: In vitro and in vivo, **Duxorel** undergoes rapid hydrolysis into its carboxylic acid derivative. In plasma and urine, the glucuronide of the carboxylic acid derivative is also observed.

#### Mechanism of Action

Clopidogrel is a prodrug, which is activated in two steps, first by CYP2C19, CYP1A2 and CYP2B6, then by CYP2C19, CYP2C9, CYP2B6 and CYP3A. The active metabolite then specifically and irreversibly inhibits the P2Y12 subtype of ADP receptor, which is important in activation of platelets and eventual cross-linking by the protein fibrin. Platelet inhibition can be demonstrated two hours after a single dose of oral **Duxorel**, but the onset of action is slow, so a loading dose of either 600 or 300 mg is administered when a rapid effect is needed.

### INDICATION AND USAGE:

**Duxorel** is used to prevent heart attacks and strokes in persons with heart disease (recent heart attack), recent stroke, or blood circulation disease (peripheral vascular disease) It is also used with aspirin to treat new/worsening chest pain (new heart attack, unstable angina) and to keep blood vessels open and prevent blood clots after certain procedures (such as cardiac stent). **Duxorel** works by blocking platelets from sticking together and prevents them from forming harmful clots. It is an antiplatelet drug. It helps to keep blood flowing smoothly in your body.

### DOSE AND ADMINISTRATION:

Always take **Duxorel** Tablets exactly as your doctor has told you. You should consult with your doctor or pharmacist if you are not sure. The usual dose is one 75mg tablet of **Duxorel** per day to be taken orally with or without food and at the same time each day You should take **Duxorel** Tablets for as long as your doctor continues to prescribe it.

### CONTRAINDICATIONS:

Hypersensitivity to **Duxorel** or to any of the excipients.

### WARNINGS AND PRECAUTIONS:

If you are allergic (hypersensitive) to **Duxorel** or any of the other ingredients in **Duxorel** Tablets. If you have a medical condition that is currently causing bleeding such as a stomach ulcer or bleeding within the brain If you suffer from severe liver disease.

### DRUG INTERACTIONS:

You should specifically tell your doctor if you take oral anticoagulants, medicines used to reduce blood clotting or non-steroidal anti-inflammatory medicine, usually used to treat painful inflammatory conditions of muscle or joints heparin or any other injectable medicine used to reduce blood clotting Omeprazole, Esomeprazole or cimetidine, medicines to treat upset stomach fluconazole, voriconazole, ciprofloxacin, or chloramphenicol, medicines used to treat bacterial and fungal infections Fluoxetine, fluvoxamine, or moclobemide, medicines to treat depression carbamazepine, or oxcarbazepine, medicines to treat some forms of epilepsy ticlopidine, other antiplatelet agent.

**POSSIBLE SIDE EFFECTS:**

Serious adverse drug reactions associated with **Duxorel** therapy include: hemorrhage may be increased by the co administration of aspirin In the CURE trial, people with acute coronary syndrome without ST elevation were treated with aspirin plus **Duxorel** or placebo and followed rates of major bleed were seen:

Any major bleeding: Duxorel 3.7%, placebo 2.7%

Life-threatening bleeding: Duxorel 2.2%, placebo 1.8%

Hemorrhagic stroke: Duxorel 0.1%, placebo 0.1%

Gastrointestinal hemorrhage: Duxorel 2.0%, aspirin 2.7%

Intracranial bleeding: Duxorel 0.4%, aspirin 0.5%

**STORAGE & INSTRUCTIONS:**

Keep out of the reach of children & Store below 30°C.

Protect from sunlight & moisture.

Improper storage may deteriorate the medicine.

Do not use this medicine after the expiry date which is stated on the blister.

**PRESENTATION:**

**Duxorel** 75mg film coated Tablet in pack of 14's.

Manufactured by :



**PHARMA LORD**

**PHARMA LORD** | 12km, Lahore  
**(PVT.) LIMITED** | Road, Layyah,  
Pakistan  
[www.pharma-lord.com](http://www.pharma-lord.com)